



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:
524-478

Date of Issuance
3/21/95

NOTICE OF PESTICIDE:
 Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance: 000
Unconditional

Name of Pesticide Product: Bacillus
thuringiensis var.
kurstaki (B.t.k.)
Insect Control
Protein produced
in cotton

Name and Address of Registrant (include ZIP Code):

Monsanto Company
700 Chesterfield Parkway North
Saint Louis, Missouri 63198

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under sec. 3(c)(2)(B) of FIFRA.

This product is registered in accordance with FIFRA sec. 3(c)(5), subject to the following terms and conditions:

1. The EPA Registration Number shall read, "EPA Reg. No. 524-478".

Signature of Approving Official: See page 2

Date: 3/21/95

275

Transformed cottonseed must be accompanied by the product notice (Grower Guide) which contains the following:

1. The *B.t.k.* delta endotoxin protein expressed in this cotton controls the listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k.* delta endotoxin protein are planted.
3. Instruction for growers to read the product notice (Grower Guide) prior to planting; for information on planting, production and insect resistance management.

BEST AVAILABLE COPY

0030F010

PLANT PESTICIDE ACTIVE INGREDIENT

Bacillus thuringiensis subsp. *kurstaki* Insect Control Protein

Pure form of the Plant Pesticide, *Bacillus thuringiensis* subsp. *kurstaki* control protein as expressed in cotton cells.

Active Ingredient:

Bacillus thuringiensis subsp. *kurstaki* delta endotoxin protein as produced by the CryIA(c) gene and its controlling sequences in cotton 0.001 - 0.006%*

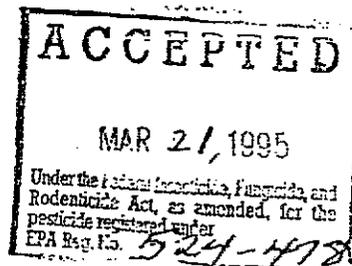
Inert:

Substances produced by marker genes and their controlling sequences in cotton 0.001 - 0.003%

*Percentage of total protein on a dry weight basis.

EPA REGISTRATION NUMBER 524-478

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198



Directions for Use:

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

The pesticide product may be used only for seed production for seed increase and breeding nurseries as specified in the terms and conditions of this registration and on the labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin protein for the control of the following lepidopteran cotton insect pests:

- | | |
|-----------------|---------------------------------|
| Cotton bollworm | <i>Helioverpa zea</i> |
| Tobacco budworm | <i>Heliothis virescens</i> |
| Pink bollworm | <i>Pectinophora gossypiella</i> |

Transformed cotton must be accompanied by a product notice that contains the following:

1. The *B.t.k.* delta endotoxin protein expressed in this cotton controls the listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are unnecessary when cotton containing the *B.t.k.* delta endotoxin protein are planted.

BEST AVAILABLE COPY

3. Instruction for growers to read the product grower guide prior to planting; for information on planting, production and insecticide resistance management.

Monsanto shall enter into a written agreement with each of its cooperators that requires the cooperator to comply with all the terms and conditions of this registration. "Cooperator" means any person who has been granted permission from Monsanto to use the pesticide product on property owned or controlled by that person.

Monsanto shall be liable under the Federal Insecticide, Fungicide and Rodenticide Act for any action of a cooperator that does not comply with the terms and conditions of this registration.

Plants that contain the pesticide product may be grown on no more than a total of 36,850 acres. Plants that contain the pesticide product may only be grown in the states of Arizona, Arkansas, California, Mississippi, South Carolina, Texas, and the territory of Puerto Rico. The maximum acres grown in each State shall be:

Summary by State and Maximum Number of Acres Proposed for Seed Increase and Breeding Nurseries of Insect Resistant Cotton

Seed Increase Acres	
<u>State</u>	<u>Total Acres</u>
Arizona	23, 500
Arkansas	2, 500
Mississippi	10, 500
<u>Territory</u>	<u>Total Acres</u>
Puerto Rico	30

Total Seed Increase Acres 36, 530

Breeding Nursery Acres	
<u>State</u>	<u>Total Acres</u>
Arizona	110
California	15
Mississippi	100
South Carolina	30
Texas	30
<u>Territory</u>	<u>Total Acres</u>
Puerto Rico	35

Total Breeding Nurseries Acres 320
 Total United States Acres 36, 850

"Seed Increase" means to increase the seed quantities of cotton cultivars containing the pesticide product. "Breeding Nursery" means transferring the pesticide product, through breeding, to cotton varieties not containing the pesticide product.

BEST AVAILABLE COPY

5 7 8

Any area with a plant that contains the pesticide product must be isolated by one of the following methods:

* Any such area may be surrounded by a border that is at least 1320 feet (one-quarter of a mile) wide and free of any cotton plant;

* Any breeding nursery acres or any seed increase acres that are 10 acres or more may be surrounded by a border that is at least 76 feet wide and that contains 24 border rows of cotton plants that do not contain the pesticide product; or

* Any breeding nursery acres or any seed increase acres that are less than 10 acres may be surrounded by a border that is at least 39 feet wide and contains 12 border rows of cotton plants that do not contain the pesticide product.

No plants or plant propagation materials that contain the pesticide product may be sold or distributed, except that such plants and materials may be distributed between Monsanto and its cooperators and may be distributed for storage under Monsanto's control; and any lint that is obtained from the seed cotton at ginning may be sold and distributed.

All plant propagation materials produced by Monsanto and its cooperators that contain the pesticide product must be either destroyed or securely stored for future plantings, research, or used for additional plant propagation material pursuant to the conditions of this registration.

All sites are to be monitored for 12 months for germinating seed which must be subsequently destroyed by mechanical cultivation, by hand or herbicide application.

After this registration expires, no plants or plant propagation materials that contain the pesticide product may be planted, grown, or harvested.

Equipment used for planting and harvesting must be carefully cleaned of seed cotton that contains this pesticide product before further use. Seed from all plots must be harvested or destroyed.

Information contained in the preceding five paragraphs apply to any plants or plant propagative materials in border rows.

The registration of this pesticide product will automatically expire on midnight of March 15, 1996, unless EPA extends the registration.

BEST AVAILABLE COPY